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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,488	05/25/2001	Anthony E. Bolton	355908-1650	4401
38706 7590 02/08/2008 FOLEY & LARDNER LLP 975 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 02/08/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/866,488	<b>Applicant(s)</b> BOLTON ET AL.	
	<b>Examiner</b> MISOOK YU	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-27, 29, 30, 46-54 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-27, 29, 30, 46-54, and 56-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Claims 19-27, 29, 30, 46-54, and 56-59 are pending and under consideration.

The art rejection of record is withdrawn in view of the amendment.

#### ***Claim Rejections - 35 USC § 103***

Claims 19-27, 29, 30, 46-54, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO92/10198.

Claims 19-27, 29, 30, 46-54, and 56-59 are drawn to method of administering apoptotic bodies with the range 10,000 to 10,000,000 apoptotic bodies per kg of body weight for treatment and/or prophylaxis of inflammation in a mammalian patients, wherein the apoptotic cells exhibits various art-known characteristics, and the apoptotic cells inhibits and induces certain physiological functions once administered.

WO92/10198 teach method of administering ex-vivo treated apoptotic bodies i.e. lymphocytes exhibiting apoptosis (note page 17, lines 10-20) for treatment of hypersensitivity, autoimmune diseases, and various other diseases (note page 7), Fig. 7.

As for the limitation, reducing Th-1 derived cytokines and up-regulating Th-2 derived cytokines, these are physiological response of administering apoptotic bodies. In other words, it is a natural phenomenon in response to administration of apoptotic cells.

As for the characteristics of apoptotic cells (i.e. DNA fragmentation, surface exposure of phosphatidylserine, etc.), the instant specification at page 2 lines 16 to page 4 discloses that each of the characteristics of apoptotic cells in the instant claims

is an alternative way of detecting whether cells undergo apoptosis or not. Therefore, it is concluded that if cells with DNA fragmentation must have surface exposed phosphatidylserine or vice versa. In addition, the specification discloses at page 4 pages 13-17 "Methods of quantifying apoptotic cells and apoptotic bodies in a cellular composition are known and readily practiced by persons of skill in the art. Techniques include staining of the treated cell population, with an appropriate, selective dye such as fluorescein-conjugated annexin V, followed by incubation and analysis by flow cytometry."

As for range in the claims, it is 100-fold in the respective base claims and very wide in the dependent claims. MPEP 716.02(d) [R-2] states that the "nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. In re Kollman, 595 F.2d 48, 201 USPQ 193 (CCPA 1979). MPEP 2144.05 [R-5] also deals with "Obviousness of Ranges", which states "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". Since the prior art teaches the claimed method, it is concluded that claimed ranges are within the optimum or workable ranges by routine experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU  
Primary Examiner  
Art Unit 1642

/Misook Yu/